Please amend the application filed on even date herewith prior to proceeding with its examination.

IN THE CLAIMS

Claims 1-28 (Cancelled).

29. (New) Process for preparing ursodeoxycholic acid di-sodium 3,7-disulfate comprising:

a) reacting ursodeoxycholic acid with sulfamic acid in dimethylformamide to give ursodeoxycholic acid di-ammonium 3,7-disulfate;

b) treating the ursodeoxycholic acid di-ammonium 3,7-disulfate with organic sodium bases or inorganic sodium bases then treating the reaction mixture with an inorganic acid until a pH between 3.0 and 4.5 is reached to give ursodeoxycholic acid di-sodium 3,7-disulfate in solution.

30. (New) Process as claimed in claim 29, wherein the reaction of stage a) is conducted at a temperature between 40°C and 110°C.

31. (New) Process as claimed in claim 30, wherein the temperature is between 80°C and 90°C.

32. (New) Process as claimed in claim 29, wherein ursodeoxycholic acid di-ammonium 3,7-disulfate is separated from the reaction mixture of stage a) by fractional crystallisation with acetone.

33. (New) Process as claimed in claim 29, wherein the inorganic sodium bases in stage b) are selected from the group consisting of sodium hydroxide, sodium carbonate and sodium bicarbonate.

34. (New) Process as claimed in claim 29, wherein the organic sodium bases are sodium acetate.

35. (New) Process as claimed in claim 29, wherein in stage b) the treatment of ursodeoxycholic acid di-ammonium 3,7-disulfate with organic sodium bases or inorganic sodium bases is conducted in alcoholic solvent.

36. (New) Process as claimed in claim 35, wherein the alcoholic solvent is selected from the group consisting of linear or branched lower C1-C4 alcohols or their mixtures.

37. (New) Process as claimed in claim 36, wherein the alcohol is methanol.

38. (New) Process as claimed in claim 29, wherein in stage b) the treatment with organic sodium bases or inorganic sodium bases is conducted at a temperature between –10°C and 30°C.

39. (New) Process as claimed in claim 38, wherein the temperature is between 0°C and 5°C.

40. (New) Process as claimed in claim 29, wherein in stage b) the treatment with organic sodium bases or inorganic sodium bases is conducted under vacuum.

41. (New) Process as claimed in claim 29, wherein in stage b) the acidification of the reaction mixture after treatment with organic sodium bases or inorganic sodium bases is conducted by treating the reaction mass with an inorganic acid selected from the group consisting of hydrochloric acid, sulphuric acid, 85% (w/w) phosphoric acid or their mixtures.

42. (New) Process as claimed in claim 41, wherein the acid is 85% phosphoric acid.

43. (New) Process as claimed in claim 29, also comprising stage c), recovering ursodeoxycholic acid di-sodium 3,7-disulfate from the reaction mixture, said stage comprising: c')

removing, by filtration, precipitated inorganic salts formed after acidification treatment and c'') precipitating ursodeoxycholic acid di-sodium 3,7-disulfate from the filtrate whereby the solution containing ursodeoxycholic acid di-sodium 3,7-disulfate is concentrated by distillation and the residue is re-dissolved in organic solvent to isolate ursodeoxycholic acid di-sodium 3,7-disulfate.

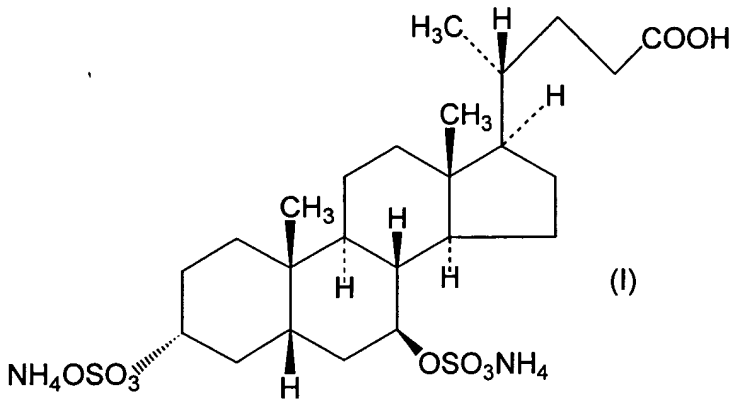
44. (New) Process as claimed in claim 41, wherein in stage c') the filtration to remove the precipitated inorganic salts formed after acidification treatment is facilitated by treating the reaction mixture derived from stage b) with an organic solvent.

45. (New) The process as claimed in claim 44, wherein said organic solvent is acetone.

46. (New) Process as claimed in claim 43 wherein in stage c'') the residue obtained by concentrating the solution containing ursodeoxycholic acid di-sodium 3,7-disulfate by distillation is re-dissolved in an organic solvent, at a temperature between 20°C and 70°C, and the suspension thus obtained is then cooled to room temperature and filtered to obtain ursodeoxycholic acid di-sodium 3,7-disulfate as precipitate.

47. (New) The process as claimed in claim 46, wherein said organic solvent is acetone and ursodeoxycholic acid di-sodium 3,7 disulfate is dissolved in said solvent at a temperature comprised between 55° and 65°C.

48. (New) Ursodeoxycholic acid di-ammonium 3,7-disulfate of formula:



(I)

49. (New) Process for synthesizing ursodeoxycholic acid di-ammonium 3,7-disulfate comprising reacting ursodeoxycholic acid with sulfamic acid in N,N-dimethylformamide.

50. (New) Process as claimed in claim 49, wherein the reaction with sulfamic acid is conducted at a temperature between 40°C and 110°C.

51. (New) Process as claimed in claim 50, wherein the temperature is between 80°C and 90°C.

52. (New) Process as claimed in claim 49, wherein the ursodeoxycholic acid di-ammonium 3,7-disulfate is separated from the reaction mixture by fractional crystallisation with acetone.